

**K240137 Cranial LOOP, Cranial LOOP L and Cranial LOOP XL
Cranial Bone Fixation System**Feb 16, 2024
29 days to decisionK240137 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k240137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cover, Burr Hole (GXR)
Date received	Jan 18, 2024
Decision date	Feb 16, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neos Surgery S.L
Location	Alexandria, VA, US
Contact	Eduard Garcia
510(k) history	6 submissions · 6 cleared · 2010-2024

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